



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,401	04/05/2006	Russell Edward Morris	9013-72	6024
20792	7590	05/06/2010		
MYERS BIGEL, SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER				
JOHNSON, KEVIN M				
ART UNIT		PAPER NUMBER		
1793				
MAIL DATE		DELIVERY MODE		
05/06/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/562,401

Applicant(s)

MORRIS ET AL.

Examiner

KEVIN M. JOHNSON

Art Unit

1793

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 42-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 42-49 is/are rejected.
- 7) ☒ Claim(s) 44-48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 2/4/2010

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 2/4/2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

2. Claims 44-48 objected to because of the following informalities: there are two claims identified as claim 44. Appropriate correction is required. For the purposes of examination the second claim 44 has been interpreted as claim 45, claim 45 as claim 46, and so on.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6 and 7 rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Langmuir 1993, 9, pp. 2337-2343).

In regard to claims 1, 2 and 4, Zhang discloses a zeolite that contains reversibly adsorbed NO (abstract). An exemplary embodiment of such a zeolite is a Na-MFI type zeolite, in which the degree of cation exchange is 100% (table I). A 100% exchanged zeolite inherently has a number of exchanged cations equivalent to, when their charge is considered, the number of aluminum atoms contained in the framework as required

by the instant claims. It should be noted that required by the instant claims any of x , y or v may be zero. The language defining the material required by the instant claims as "a pharmaceutical, nutraceutical or cosmetic preparation" is considered to be directed to an intended use of the material and the material disclosed by the prior art possesses an inherent capability for these uses as it meets all the requirements of the instant claims.

In regard to claim 3, the material disclosed by Zhang meets the requirements of the instant claims, as both x and y may be zero.

In regard to claim 6, the zeolite material is in the form of a powder (p. 2338, IR measurement).

In regard to claim 7, Zhang teaches that a self-supporting monolith may be formed from the powder by compressing the powder for 30 minutes (p. 2338, IR measurement).

In regard to claim 43, the material disclosed by Zhang is dried prior to NO adsorption (page 2338, column 1).

5. Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Rudolf et al. (Journal of Magnetic Resonance, 2002, 155, pp. 45-56).

In regard to claims 1 and 5, Rudolf discloses a sodium exchanged type-A zeolite, Na-A, for use in the adsorption and desorption of NO. Zeolite-A has the LTA structure required by the instant claims. The language defining the material required by the instant claims as "a pharmaceutical, nutraceutical or cosmetic preparation" is considered to be directed to an intended use of the material and the material disclosed

by the prior art possesses an inherent be capability for these uses as it meets all the requirements of the instant claims.

In regard to claim 6, the zeolites taught by Rudolf are microcrystalline powders (p. 47, column 1).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 8 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang as applied to claim 7 above, and further in view of Wu (US 5492883).

In regard to claim 8, Zhang teaches that the powder may be formed in to a monolith, but fails to teach the inclusion of a binder.

Wu discloses a method of combining a zeolite material and an organic binder, and then extruding the composition to form a monolithic structure (column 3, lines 50-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a binder as disclosed by Wu in the formation of the monolith taught by Zhang. Such a modification would have been motivated by the teaching in Zhang that the zeolite material may be formed in to a monolith, and the disclosure by Wu of a method for the formation of a zeolite containing monolith incorporating a binder.

In regard to claim 42, Wu discloses that the binders may consist of polymers, such as polyvinyl alcohols (column 5, lines 54-59). The instant claim depends from claim 8, which requires that the binder be "selected from ceramic binders, polymeric binders and other polymers." The limitations in the instant claim regarding the materials that are considered ceramic binders and polymeric binders do not place any limitations on the "other polymers" classification of the parent claim nor limit the binder selection to only the ceramic and polymeric binder classifications. The polyvinyl alcohol binder disclosed by Wu therefore meets the requirements of the instant claim because, as the

limitations on the ceramic and polymeric binder classifications in the instant claim make clear, it would be classified in the "other polymers" group.

10. Claims 44, 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang as applied to claim 1 above, and further in view of Green et al. (US 5814666) and Yamamoto et al. (JP 08092051 A).

In regard to claims 44, 46 and 49, Zhang fails to disclose that the composition includes a carrier.

Green discloses that compositions capable of releasing nitric oxide have an antimicrobial effect (column 4, lines 37-47).

Yamamoto discloses a deodorizing cosmetic. The composition comprises an antimicrobial zeolite and a silicone carrier (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the zeolite disclosed by Zhang in the carrier containing deodorizing cosmetic composition disclosed by Yamamoto. Such a modification would have been motivated by the teaching in Yamamoto that the composition includes antimicrobial zeolites, and the disclosure in Green that materials capable of releasing nitric oxide exhibit antimicrobial functionality and the disclosure in Zhang of zeolites have the capability to release adsorbed nitric oxide.

11. Claims 45, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang as applied to claim 1 above, and further in view of Green and Barry et al. (US 00/64506 A1).

In regard to claims 45, 47 and 48, Zhang fails to disclose that the material is included in a medical article meeting the requirements of the instant claims.

Green discloses that compositions capable of releasing nitric oxide have an antimicrobial effect (column 4, lines 37-47).

Barry discloses a stent that incorporates an antimicrobial agent. The antimicrobial agent is preferably a zeolite that exhibits antimicrobial activity (page 3, lines 2-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the zeolite material disclosed by Zhang in the stent described by Barry. Such a modification would have been motivated by the teaching in Green that materials capable of releasing nitric oxide exhibit antimicrobial functionality, Zhang's disclosure of zeolites have the capability to release adsorbed nitric oxide and the teaching in Barry that zeolites with antimicrobial functionality may be beneficially included in stents.

Response to Arguments

Applicant's arguments filed 1/26/2010 have been fully considered but they are not persuasive.

The argument that the requirement in the instant claims of a cosmetic, pharmaceutical or nutraceutical composition overcomes the rejections based on Zhang and Rudolf is not persuasive. The language defining the material required by the instant claims as "a pharmaceutical, nutraceutical or cosmetic preparation" is considered to be directed to an intended use of the material. The instant disclosure

does not indicate that structural limitations beyond those explicitly contained in the instant claims are implied by this intended use limitation. The zeolite materials disclosed by Zhang and Rudolf that contain releasably adsorbed NO meet all the requirements of the instant claims, and therefore would inherently possess the same capabilities as the material required by the instant claims.

Conclusion

Applicant's amendment, the addition of claims 42-49, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN M. JOHNSON whose telephone number is (571)270-3584. The examiner can normally be reached on Monday-Friday 9:00 AM to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Mayes can be reached on 571-272-1234. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin M Johnson/
Examiner, Art Unit 1793

/David M Brunsman/
Primary Examiner, Art Unit 1793